

510(k) summary for the CARTO™ XP EP Navigation System

510(k) Notification submitted by:

Biosense Webster, Inc.
3333 Diamond Canyon Rd.
Diamond Bar, CA 91765
USA
Phone: +1-800-729-9010
Fax: +1-909-839-8804

JAN 09 2003

Contact person:

Marcia Yaross
Vice President, Regulatory and Clinical Affairs

Proprietary device name:

CARTO™ XP EP Navigation System with
QWIKMAP™ software

Classification name:

Programmable diagnostic computer
(per 21 CFR 870.1425)

Common device name:

Cardiac Mapping System

Predicate device:

CARTO™ XP mapping system
510(k) No. K013083

Manufacturer:

Biosense Webster (Israel) Ltd.
POB 2009
Tirat HaCarmel, 39120
Israel

Indications For Use

The CARTO XP EP Navigation System with QWIKMAP software is intended to acquire real time catheter based cardiac electrophysiological maps in patients who are eligible for a conventional electrophysiological study. There are no special contraindications when using the CARTO XP with QWIKMAP software.

General Device Description

The CARTO XP EP Navigation system with QWIKMAP software is designed to acquire, analyze, and display electro-anatomical maps of the human heart. The maps are reconstructed using the combination of information gathered from the integration of intracardiac electrograms with their respective endocardial locations. Maps may be displayed as electrical activation maps, electrical propagation maps, electrical potential maps, chamber geometry maps, and impedance maps. In the CARTO XP with QWIKMAP mapping system the location information needed to create the cardiac maps is acquired using catheters equipped with magnetic proximal and distal location sensors. The

acquired patient signals, including body surface ECG and intracardiac electrograms may also be displayed in real time on the display screen.

Cardiac EP mapping procedures are generally performed using a roving mapping catheter, a computerized mapping system, and fluoroscopy to determine the location of the tip of the mapping catheter. In the conventional procedure both the patient and the physician are exposed to harmful ionizing radiation during the course of the lengthy procedure. The CARTO XP with QWIKMAP mapping system enables cardiac mapping using a magnetic location technology, and may reduce exposure to dangerous ionizing radiation.

Safety and Effectiveness

The CARTO™ XP EP Navigation System with QWIKMAP™ software complies with the following safety standards:

- UL 2601-1: 97/CSA C22.2 No. 601.1
- IEC 60601-2-25: 93 and A1(99)
- IEC 60601-2-27: 94

The non-clinical bench and animal testing show that the device is as safe and as effective as the previously marketed device to which it is being compared and does not raise any new questions of safety or effectiveness.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 09 2003

Biosense Webster, Inc.
c/o Mr. William Welch, RAC
Regulatory Affairs Project Manager
3333 Diamond Canyon Rd.
Diamond Bar, CA 91765

Re: K020863
Trade Name: Carto™ XP EP Navigation System
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II (two)
Product Code: DQK
Dated: August 9, 2002
Received: August 12, 2002

Dear Mr. Welch:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

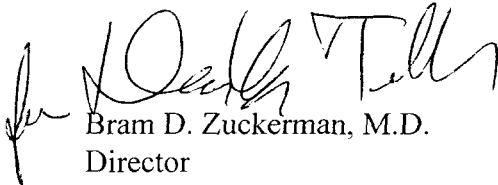
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman". The signature is stylized with a large "B" and "Z".

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for use statement


510(k) No: K020863

Device Name: CARTO XP EP Navigation System

Indications For Use:

The intended use of the CARTO XP EP Navigation System is catheter-based atrial and ventricular mapping.

The CARTO XP EP Navigation System allows real-time display of cardiac maps in a number of different formats. Maps may be displayed as cardiac electrical activation maps, cardiac electrical propagation maps, cardiac electrical potential maps, cardiac chamber geometry maps and cardiac impedance maps. The acquired patient signals, including body surface ECG and intracardiac electrograms may also be displayed in real time on the display screen.


(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K020863

Prescription Use ☒